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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,950	07/23/2001	Shripad S. Bhagwat	10624-047-999	3712

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PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER

STOCKTON, LAURA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 07/31/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/910,950

Applicant(s)

BHAGWAT ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,6,10-13,18-20,22-69,71-93,98-110 and 114-119 is/are pending in the application.
- 4a) Of the above claim(s) 22-69,75-84,86 and 87 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6,10-12,89-92,106-109 and 117 is/are allowed.
- 6) ☒ Claim(s) 5, 13, 18-20, 71-74, 85, 88, 93, 98-105, 114-116, 118 and 119 is/are rejected.
- 7) ☒ Claim(s) 110 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 5, 6, 10-13, 18-20, 22-69, 71-93, 98-110 and 114-119 are pending in the application.

Election/Restrictions

Applicants' election of Group I in Paper No. 6 without traverse was acknowledged in the previous Office Action. The requirement was deemed proper and made FINAL in the previous Office Action.

Claims 22-69, 75-84, 86 and 87 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Rejections made in the previous Office Action which do not appear below have been overcome. Therefore, arguments pertaining to these rejections will not be addressed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 118 is rejected under 35 U.S.C. 102(a) as being anticipated by Boehm et al. {Journal of Medicinal Chemistry (July 13, 2000), 43(14), pages 2664-2674}.

Boehm et al. disclose compound 5 at the top of page 2669 (or CA Registry No. 293758-67-5) which is embraced by the instant claimed invention.

Claim 119 is rejected under 35 U.S.C. 102(b) as being anticipated by:

- a) Andronati et al. {CA 122:314528, 1995} – see the compound of CA Registry No. 57614-16-1;
- b) Fujimura et al. {CA 107:198159, 1987} – see the compound of CA Registry No. 57614-16-1; and
- c) Fujimura et al. {CA 84:31053, 1976} – see the compound of CA Registry No. 57614-16-1.

Each of the above cited references disclose products embraced by the instant claims.

Claims 13 and 93 are rejected under 35 U.S.C. 102(e) as being anticipated by Reich et al. {U.S. 2002/0161022}.

Reich et al. disclose products that are embraced by the instant claims, which are useful in diseases/disorders such as cancer, rheumatoid arthritis, etc. See, for example, compounds 84 and 85 on page 94.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 13, 18-20, 71-74, 85, 88, 93, 98-105, 114-116, 118 and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich et al. {U.S. 2002/0161022}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim indazole products. Reich et al. teach indazole products which are either structurally the same as the instant claimed products (see above 102 rejections) or structurally similar to the instant

claimed products, which are useful in treating, for example, rheumatoid arthritis. See, for example, formula (II) on page 4 wherein R'_1 is $-CR_4=CR_4X$, R_4 is hydrogen, X is a substituted aryl and R'_2 is a heteroaryl or see compounds 84 and 85 on page 94.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between some of the products of the prior art and the products instantly claimed is that of generic description.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating rheumatoid arthritis).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, rheumatoid arthritis. The instant

claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicants' arguments filed May 27, 2003 have been fully considered. In regard to the claims rejected under 35 USC § 102(e), Applicants argue that nowhere in Reich et al. are compounds disclosed wherein R_2 is $-(CH_2)_bNR_5R_6$. In response, Reich et al. disclose compounds 84 and 85 on page 94 which anticipate the instant amended claims. Compounds 84 and 85 have an amino group and a benzylamino group at the 5-position of the indazole ring which corresponds to the instant R_2 variable.

In regard to the claims rejected under 35 USC § 103, Applicants argue that: (1) nowhere in Reich et al. are compounds disclosed wherein R_2 is $-(CH_2)_bNR_5R_6$; and (2) Reich et al. do not disclose or suggest compounds wherein R_2 is a triazole, tetrazole or imidazole.

All of Applicants' arguments have been considered but have not been found persuasive. As stated above, Reich et al. disclose compounds 84 and 85 on page 94 which anticipate the instant amended claims. Compounds 84 and 85 have an amino group and a benzylamino group at the 5-position of the indazole ring which corresponds to the instant R_2 variable. Further, the R_2 variable does not represent only triazole, tetrazole or imidazole in all of the instant claims. Therefore, Applicants are arguing limitations which are not present in all of the instant claims under examination. Additionally, preferred aryl and heteroaryl groups (e.g., triazole, tetrazole and imidazole) are taught on page 7, paragraph [0076] of Reich et al. For all the reasons given above, the rejections are proper and are maintained.

Allowable Subject Matter

Claims 6, 10-12, 89-92, 106-109 and 117 are allowed over the art of record.

Claim 110 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and

any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims drawn to inventions nonelected without traverse in Paper No. 6. A complete reply, if any, to the final rejection must include cancellation of nonelected claims (37 CFR 1.144).
See MPEP § 821.01.

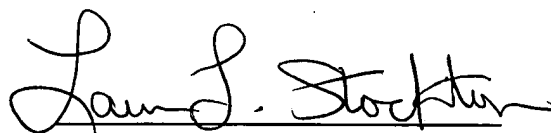
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

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The fax phone number for the organization where this application
or proceeding is assigned is (703) 308-4556.

A handwritten signature in black ink, reading "Laura L. Stockton". The signature is fluid and cursive, with the first name "Laura" and last name "Stockton" clearly distinguishable.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

July 29, 2003